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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,220	03/22/2004	Kazunari Yamaguchi	Q80490	9623

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 10/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/805,220	YAMAGUCHI ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/19/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

New claims 17-23 are pending and under examination. Applicant's election with traverse of SEQ ID NO: 8 in response to the second restriction requirement of July 31, 2006, is acknowledged. Applicant argues that the search of SEQ ID NO: 5-8 would not be a serious burden.

At the outset, the Office notes that the restriction requirement of July 31, 2006 was not a species election. In response to Applicant's argument, the Office has aligned SEQ ID NO: 5-8 and determined that SEQ ID NO: 6 and 8 are species because they share structure and function. Similarly, SEQ ID NO: 5 and 7 share structure and function.

SEQ ID NO: 5 G N T T V E S G R L S G G R R R S P D

SEQ ID NO: 7 G N A T I G S G R L P G G R R R S P D

SEQ ID NO: 6 G L T K T K E D S L G C T D P

SEQ ID NO: 8 G V T L T T E D P K E C T D P

However, SEQ ID NO: 5 and 7 do not share structure with SEQ ID NO: 6 and 8 (see below, underlined portions show shared amino acids). Thus, a search of all sequences would be a serious burden since each sequence must be run through both patent and non-patent literature databases. The Office deems that SEQ ID NO: 6 and 8 are species, of which Applicant has elected SEQ ID NO: 8.

SEQ ID NO: 5 and 7 are not considered to be species that belong to SEQ ID NO: 6 and 8 because they do not meet the requirements of a Markush group and they do not meet the test set out in *In re Harnisch* which requires that the members of the group share a common utility and also have a substantial structural feature. *In re Harnisch*, 631 F.2d 716, 206, USPQ 300 (CCPA

1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group:

(1) share a common utility, **and**

(2) share a substantial structural feature essential to that utility.

In this case, SEQ ID NO: 6 and 8 share a common utility and a substantial structural feature essential to that utility (p10). SEQ ID NO: 5 and 7 share a common utility and a substantial structural feature essential to that utility (p10). SEQ ID NO: 6 and 8, collectively, and SEQ ID NO: 5 and 7, collectively, share a common utility but do not share a substantial structural feature essential to that utility. Therefore, the restriction requirement is deemed proper and made FINAL.

The objection to the abstract of the disclosure is withdrawn in view of Applicant's amendment to the abstract.

The rejection of claims 1-7 and 11-16 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is moot in view of the cancellation of claims 1-7 and 11-16.

The rejection of claims 1-7 and 11-16 under 35 U.S.C. 102(b) as being anticipated by Yamaguchi *et al.* (*Annals of Clinical Biochemistry*, July 2001, vol. 38, pages 348-355, "Yamaguchi"), is moot in view of the cancellation of claims 1-7 and 11-16.

Claims Summary and Interpretation

The new claims are drawn to a method for detecting IgM and IgG antibody to Borna Disease Virus (BDV). The method comprises:

(a) providing a support sensitized with a BDV polypeptide;

(b) reacting the polypeptide with an anti-BDV antibody from a sample;

(c) detecting both IgM and IgG antibody.

It is understood that step (c) encompasses the ability to assay for the presence of IgM and IgG. Depending on the stage of infection, one may detect only IgM if no IgG is present, or vice versa; or one may detect both at the same time if the class switching is not yet complete. Step (c) does not mean that one will necessarily detect both IgM and IgG just by doing the assay; it depends on the stage of infection. The instant assay has the ability to detect both IgM and IgG, if both are present.

The BDV polypeptide is selected from the group consisting of the p10 region, the p24 region, and the p40 region of BDV. Specifically, the polypeptide from the p24 region is SEQ ID NO: 1. The polypeptide from the p40 region is SEQ ID NO: 3. The polypeptide from the p10 region is SEQ ID NO: 8. In another embodiment, the BDV has a property in which the class switching from the IgM antibody to the IgG antibody of immunoglobulin antibodies raised against the BDV is achieved after two months following the appearance of the IgM antibody. The infectivity and resulting IgM response and class switch to IgG is a property of BDV that is inherent and does not lend patentability to the claimed method.

Claim Rejections - 35 USC § 102

(*New Rejection*) Claims 17-19 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Hatalski *et al.* (*Journal of Virology*, February 1995, 69(2):741-747, "Hatalski"). The claims are summarized above. Hatalski discloses the detection of neutralizing antibodies to p40, p23 and gp18 in BDV-infected rats (abstract). Hatalski tested for the presence of both IgG and IgM antibodies to recombinant and native BDV proteins using electrochemiluminescence (page 741, second column, section entitled, "SDS-PAGE, Western blot and immunoprecipitation (IP)").

With regard to the limitation in the claims in step (a) about the support that is sensitized with a BDV antigen polypeptide, Hatalski's use of the ECL kit (electrochemiluminescence) makes use of a support sensitized with Hatalski's antigens. With regard to the limitation in step (b) about reacting the BDV antigen polypeptide with the anti-BDV antibody in a sample from a living body, the primary antibodies are expected to be from the sera of living subjects. Therefore, the ECL assay described in Hatalski anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 17-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamaguchi *et al.* (*Ann. Clin. Biochem.* 2001, 38:348-355, "Yamaguchi"), in view of Watanabe *et al.* (*J. Vet.*

Med. Sci., 2000, 62(7):775-778, "Watanabe"), evidenced by Planz *et al.* (*Journal of Virology*, 1999, 73(8):6251-6256, "Planz"), and further in view of Hatalski *et al.* (*Journal of Virology*, February 1995, 69(2):741-747, "Hatalski"), and Carbone, K.M. (*Clin. Micro. Rev.*, 2001, 14(3):513-527, "Carbone").

Yamaguchi discloses a synthetic peptide-based electrochemiluminescence immunoassay (ECLIA) for anti-BDV p40 and p24 IgG antibodies in rat and horse serum. Yamaguchi teaches the synthesis of 13 peptides having hydrophilic BDV p40 and p24 sequences that were fixed into microbeads. Table 1 discloses a p40 peptide that is identical to Applicant's SEQ ID NO: 3 (PKRRLVDDADAMEDQDLY), and a p24 peptide that is identical to Applicant's SEQ ID NO: 1 (QPVDQLLKDLRKNPS). Rabbit anti-BDV p40 or p24 antiserum was detected by ECLIA immunoassay. ECLIA assay involves the use of an electrode and measurement of photons emitted from the secondary antibodies bound to the BDV antibody-antigen complexes (page 350, first column). The ECLIA method is an immune agglutination reaction method (antigen-antibody binding), and is a fine particle counting method (electrode-photon). Yamaguchi is silent on the use of the antigen polypeptide of p10 (SEQ ID NO: 8) and the aspect of testing for both IgM and IgG antibodies.

However, Watanabe discloses a study on the time course for appearance to antibodies to BDV antigens p40, p24, p18 and p10. Watanabe found that anti-p10 antibodies (IgG) were detected in sera of BDV-infected rats as early as anti-p40 and anti-p24 antibodies (abstract). Watanabe's findings are indicated as useful for establishing diagnostic methods for BDV infection and for understanding its pathogenesis and replication (page 777, second column, last paragraph). It would have been obvious to include the detection of p10 in Yamaguchi's method.

One would have motivated to detect anti-p10 antibodies, as well as anti-p40 and anti-p24 antibodies for the purpose of increasing the sensitivity of Yamaguchi's method. Watanabe suggests that antibodies to individual viral proteins and BDV-specific antigens is useful for establishing diagnostic methods (page 777, second column, last paragraph). One would have had a reasonable expectation of success given that Watanabe found anti-p10, anti-p24 and anti-p40 antibodies in serum at the same time (abstract).

Neither Yamaguchi nor Watanabe disclose SEQ ID NO: 8. While Watanabe discloses the use of p10, the sequence of p10 is not disclosed in the Watanabe reference. However, as evidenced by Planz, the sequence of p10 includes SEQ ID NO: 8.

Hatalski discloses the detection of neutralizing antibodies to p40, p23 and gp18 in BDV-infected rats (abstract). Hatalski tested for the presence of both IgG and IgM antibodies to recombinant and native BDV proteins using electrochemiluminescence (page 741, second column, section entitled, "SDS-PAGE, Western blot and immunoprecipitation (IP)"). One would have been motivated to modify Yamaguchi's method by testing for the presence of IgM as well as IgG in order to detect infection as early as possible. Carbone discloses that the first serological evidence of virus infection is often IgM antibody. IgG appears as the immune response matures (page 516, first column, second full paragraph entitled, "Anti-BDV antibody detection"). Given that Hatalski demonstrates that IgM is present in response to BDV infection, and Carbone indicates that IgM is often the first serological evidence of BDV infection, one would have had a reasonable expectation of success that testing for the presence of IgM and IgG would have worked in Yamaguchi's method.

Therefore, the invention as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Stacy B. Chen 10/26/06

STACY B. CHEN
PRIMARY EXAMINER